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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/853,292	05/09/97	TOVEY M	23164-1003

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EXAMINER	
ANDRES, J	
ART UNIT	**PAPER NUMBER**
1646	

DATE MAILED: 07/18/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No.	Applicant(s)	
	08/853,292	TOVEY, MICHAEL GERARD	
	Examiner	Art Unit	
	Janet L Andres	1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-5,7-13 and 15-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-5,7-13,15-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

a)☐ All b)☐ Some * c)☐ None of the CERTIFIED copies of the priority documents have been:

1.☐ received.

2.☐ received in Application No. (Series Code / Serial Number) _____ .

3.☐ received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. & 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Response to Amendment

The receipt of amendments filed on March 21, 2000 and May 2, 2000 is acknowledged. Claims 1-5, 7-13, and 15-24 are now pending in this application. The text of those sections of Title 35, U.S. code not included in this action can be found in a previous office action.

Claim Rejections Withdrawn

1. Applicant's cancellation of claim 14 removes the basis of the rejection of claims 13 and 14 as being duplicative. This rejection is therefore withdrawn.

2. Applicant's amendment of claim 2 to describe a dosage range of 1500 IU/day to 20 x 10^6 IU/day obviates the rejection of claim 2 as being anticipated by Cummins ('382) and this rejection is therefore withdrawn.

3. Applicant's amendment of claims 1 and 2 to include the limitation of "the mammal having such a condition" obviates the rejection of claims 1-5, 7, 8, and 10-12 as being anticipated by Samo et al. (J. Infect. Dis. 1984) and this rejection is therefore withdrawn. This amendment further obviates the rejection of claims 1-3, 5, 7, 8, and 13 as being anticipated by Iida et al. (Vaccine, 1984) and this rejection is therefore also withdrawn.

4. Applicant's amendment of claim 1 obviates the rejection of claim 9 as being obvious in view of Iida et al. and this rejection is therefore withdrawn.

Claim Rejections Maintained/New Grounds of Rejection

The following rejections are made on new grounds necessitated by applicant's amendment:

5. Amended claim 15 and dependent claims 16-18 and 24 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This claim includes the limitation of " a vehicle or excipient which facilitates contact with the mucosal lining of the mouth or throat". The specification, however, does not describe a vehicle in such a way that said vehicle would be considered to be different from a merely acceptable carrier. One of skill in the art would not know from the specification as originally filed that applicant was in possession of a vehicle or excipient that would facilitate mucosal contact.

6. Amended claim 15 and dependent claims 16-18 and 24 are also rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Applicant does not describe the special qualities of a "vehicle or excipient which facilitates contact with the mucosal lining" that would distinguish it from an ordinary carrier. One of skill in the art would thus not know what vehicle or excipient is intended by applicant.

7. Claim 9 is newly rejected under 35 U.S.C. 103 as being unpatentable over Cummins in view of Iida et al. Cummins teaches the use of interferon in the treatment of viral infection but fails to teach any other cytokines. Iida et al. teaches that IFN, G-CSF, and

GM-CSF all have beneficial effects and further teaches intranasal administration. As stated in a previous action, oromucosal administration reasonably encompasses intranasal administration and the combination of two agents known to be beneficial individually is prima facie obvious.

8. The rejection of claims 15-18 as being anticipated by Samo et al. is maintained. Applicant has withdrawn the argument that Samo et al. does not encompass oromucosal contact in the paper no. 19, filed May 2, 2000. The compositions are not altered by the amendment affecting their use and the basis for rejection has therefore not changed.

9. The rejection of claims 1-5 and 7-21 under 35 U.S.C.103(a) as being unpatentable over Cummins in view of either Samo et al. or Iida et al. is maintained and newly applied to claims 22-24. Applicant argues in the communication of March 21, 2000 that the dose range of the instant application is not obvious because Cummins teaches away from higher dose, and Iida et al. and Samo et al. use different methods of administration. This argument remains unpersuasive. As stated above, applicant has withdrawn the argument that Samo et al. does not encompass oromucosal contact in the paper no. 19, filed May 2, 2000. As discussed previously on this record, the prior art fairly provides motivation to use doses higher than those exemplified by Cummins but lower than those exemplified by Sumo et al. and Iida et al., because all of the prior art dosages were found to be effective for treatment of viral infection. The artisan would reasonably have expected that any intermediate range would likewise be effective. Further, one of ordinary skill would expect that administration of higher doses would

result in absorbed levels at least equivalent to those resulting from the doses used by Cummins, and thus one of ordinary skill would expect that the higher doses of the instant application would result in effective treatment of a viral infection. Applicant's argument that Cummins (1999) continues to teach away from higher doses is not persuasive; post-filing evidence is irrelevant to what one of ordinary skill would have known at the time of filing. New claims 22 and 23 do not patentably distinguish over the prior art because the dosage range of claim 22 is within the limitations of claim 1, and claim 23, which specifies contact with the "mouth and/or throat", does not alter the limitations of claim 1, which specifies "oromucosal contact". The composition of claim 24 adds formulations anticipated by Cummins (columns 13 and 14). The rejection of claims 1-5 and 7-21 is therefore newly applied to these claims.

10. The examiner believes that she has addressed all pertinent arguments. NO CLAIM IS ALLOWED.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet Andres, Ph.D., whose telephone number is (703) 305-0557. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached at (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via internet email regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [**yvonne.eyler@uspto.gov**].

All Internet email communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark Office on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Janet L. Andres, Ph.D.
July 14, 2000

YVONNE EYLER, PH.D
PRIMARY EXAMINER